

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X	
ESPERION THERAPEUTICS, INC.,	:
	:
Plaintiff,	:
	:
-against-	:
	:
DAIICHI SANKYO EUROPE GMBH,	:
	:
Defendant.	:
	:
-----X	

No. 1:23-cv-02568-ER

Oral Argument Requested

**ESPERION THERAPEUTICS, INC.’S MEMORANDUM OF LAW IN SUPPORT OF
ITS MOTION FOR JUDGMENT ON THE PLEADINGS**

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PRELIMINARY STATEMENT

This case turns on the plain language of an unambiguous contract. DSE promised to pay Esperion \$300 million if Esperion’s life-saving drugs met certain performance metrics in a clinical trial and received regulatory approval. DSE is now trying to renege on its promise, claiming that the contract does not actually say what it so clearly does. DSE is attempting to drive Esperion into bankruptcy by forcing it to litigate all the way to trial on a legal question that can and should be readily adjudicated on the pleadings. The allegations in Esperion’s amended complaint, and DSE’s binding admissions in its answer, establish there is no material factual dispute, and this Court can declare the contract’s meaning as a matter of law.

Section 9.2 of the contract requires DSE to pay Esperion a “Regulatory Milestone Payment” if certain conditions are met. At the time the contract was signed, Esperion was conducting and funding a clinical study to measure how effectively its drugs reduced major cardiovascular risks such as heart attack and stroke. Once the study was complete, Esperion would apply for regulatory approval of a label in Europe. That label would include the indication for which the drugs should be used, along with the results of the study. The contract requires DSE to pay Esperion \$300 million if Esperion obtains a label that includes an indication for “cardiovascular risk reduction,” and also includes “a result” of the clinical study demonstrating a 20% reduction in cardiovascular risk.

The question presented here is straightforward: Does the contract provide that *any one of several cardiovascular risk reduction results* from the study triggers DSE’s payment obligation (as Esperion argues)—or is the payment obligation triggered by *only one particular result* (as DSE argues)?

This pure question of contract interpretation is not a close one. The contract is

unambiguous and its plain language resolves this case. The parties’ deliberate choice of the indefinite article—“*a* result”—recognizes that the study would yield multiple results showing the requisite level of cardiovascular risk reduction, and that any one of those results could trigger DSE’s payment obligation. For well over a century, New York courts have read the word “a” in this way, confirming that “use of the indefinite article . . . ‘a’” refers “to any one of” several possibilities. *Van Brunt v. Van Brunt*, 111 N.Y. 178, 185 (1888).

Esperion’s plain-language reading is confirmed by well-settled canons of construction. *First*, general terms in a contract may not be arbitrarily limited but given their full scope, and here the general term “a result” must be understood to mean *any* result rather than one particular result. *Second*, contracts must be construed to avoid superfluity, and DSE’s interpretation would render meaningless the neighboring provision in Section 9.2 that the “milestone payment shall be payable only once”—a provision that has meaning only if multiple results could trigger payment.

DSE’s interpretation, in contrast, defies the plain language of the contract and runs roughshod over the canons of construction. DSE says the parties conditioned payment on one, and only one, particular result: a composite metric known as MACE-4 that is not mentioned in Section 9.2 or anywhere else in the 84-page contract. If the parties—represented in the contract negotiations by sophisticated counsel—wanted to condition payment on one particular result, they could and would have said so. Instead, they used a general phrase—“a result”—rather than the more specific, technical term (MACE-4) that DSE now asks the Court to read into the contract. Courts do not insert missing words into contracts—particularly a highly specialized term of art that appears nowhere in the 84-page Agreement.

There are no factual disputes that could impede a declaratory judgment. In a binding admission, DSE acknowledged in its answer that the study included multiple “results” that

demonstrated “a reduced risk of certain adverse cardiovascular events.” Esperion’s amended complaint and DSE’s answer confirm that the only disputed question is one of law—a pure question of contract interpretation. And there is no need for the Court to receive extrinsic evidence that might bear on the contract’s meaning, as consideration of extrinsic evidence is forbidden where, as here, a contract is unambiguous.

Not only is a judgment on the pleadings permissible based on this record, it is urgently needed. DSE’s repudiation of its obligation has driven Esperion’s stock to record lows and devastated its finances. DSE knows this case is existential for Esperion, and is acting tactically. It knows that Esperion (a small Michigan-based company) is unable to match the resources DSE (a European affiliate of a large Japanese pharmaceutical concern) can commit to discovery. DSE knows that Esperion cannot afford the long road to trial, so it has every incentive to manufacture impediments to a Rule 12(c) ruling in hopes of delaying a final judgment until Esperion is too weak to fight back.

The Court should grant judgment in Esperion’s favor on its single-count declaratory judgment claim. It should declare that *any* result of the clinical study demonstrating cardiovascular risk reduction of 20% triggers DSE’s payment obligation.

BACKGROUND

I. Esperion And DSE Sign The Agreement, Which Entitles Esperion To A Regulatory Milestone Payment Based On “A Result” Of The CLEAR Outcomes Study.

Esperion is a Michigan-based company that manufactures life-saving drugs to treat cardiovascular disease. (FAC ¶ 2; Answer ¶ 2.)¹ High levels of LDL cholesterol can contribute to heart disease and increase risk of heart attacks, strokes, and other cardiovascular and other health

¹ “FAC” refers to Esperion’s First Amended Complaint, Dkt. No. 20. “Answer” refers to DSE’s Answer, Dkt. No. 33.

problems. (FAC ¶ 21; Answer ¶ 21.) Statins are a common treatment for patients with high LDL cholesterol (commonly referred to as “bad” cholesterol), but millions of patients around the world are “statin intolerant,” meaning they cannot take statins at all or cannot tolerate a sufficient dose of statins. (FAC ¶¶ 2, 22; Answer ¶¶ 2, 22.) Esperion developed bempedoic acid as a treatment option for statin intolerant patients to lower LDL cholesterol and reduce the risk of heart disease. (FAC ¶¶ 20, 23; Answer ¶¶ 20, 23.)

By 2018, Esperion was looking for a partner to commercialize and sell its bempedoic acid products in Europe. (FAC ¶ 29; Answer ¶ 29.) Esperion discussed such a partnership with DSE, the European affiliate of Daiichi Sankyo Company, Ltd., a large pharmaceutical company based in Japan. (FAC ¶¶ 3, 29; Answer ¶¶ 3, 29.) In January 2019, Esperion and DSE signed a License and Collaboration Agreement (“Agreement”), which granted DSE an exclusive license to sell Esperion’s bempedoic-acid drugs in Europe. (FAC ¶¶ 3, 43; Answer ¶¶ 3, 43.) The Agreement was an arm’s-length commercial transaction negotiated between sophisticated parties who were represented by experienced counsel. (FAC ¶ 35; Answer ¶ 35.) The Agreement is governed by New York law. (FAC ¶ 43; Answer ¶ 43; Agmt. § 14.3.)

When the parties signed the Agreement, the initial phases of the CLEAR Outcomes Study (the “Study”)—a landmark clinical trial that Esperion sponsored and funded—were underway. (FAC ¶¶ 3, 27; Answer ¶¶ 3, 27.) The Study was a randomized, double-blind, placebo-controlled study designed to evaluate whether bempedoic acid reduces the risk of adverse cardiovascular events in patients who are statin intolerant. (FAC ¶ 27; Answer ¶ 27.) Once the Study was complete, Esperion would apply for regulatory approval of a revised label in Europe for Esperion’s bempedoic-acid drugs. (Agmt. § 3.2.2; Answer ¶ 48.) The label would include an indication for which the drugs should be used, along with the results of the Study. (*Id.*)

In exchange for the exclusive right to sell Esperion's bempedoic-acid drugs in Europe, DSE agreed to pay Esperion royalties and up to \$900 million in payments tied to certain regulatory and commercial milestones. (FAC ¶ 4; Answer ¶ 4.) One of those milestones was based on regulatory approval of a label for Esperion's bempedoic-acid drugs. In Section 9.2 of the Agreement, the parties agreed that DSE would make a "Regulatory Milestone Payment" (the "Payment") to Esperion if Esperion obtained regulatory approval of a label that includes an indication for "cardiovascular risk reduction" "that correlates with" certain contractual thresholds:

<p>9.2. Regulatory Milestone Payment. Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within thirty (30) days following receipt of such invoice. This milestone payment shall be payable only once.</p>	
Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	\$200,000,000
Equal to or greater than 20%	\$300,000,000

(Agmt. § 9.2.) The parties further agreed that "[t]his milestone payment shall be payable only once." (*Id.*)

II. The CLEAR Outcomes Study Results Demonstrate That Bempedoic Acid Significantly Reduces Cardiovascular Risk.

The Study concluded in November 2022. (FAC ¶ 6; Answer ¶ 6.) The Study yielded multiple results demonstrating a reduced risk of certain adverse cardiovascular events. (FAC ¶¶ 28, 54; Answer ¶¶ 28, 54.) The Study's results include a 27% reduction in nonfatal heart attacks, 23% reduction in fatal and nonfatal heart attacks, 19% reduction in coronary revascularization (severe blockage of the arteries), 15% reduction in fatal and nonfatal stroke, 15% reduction in MACE-3 (a composite of cardiovascular death, nonfatal heart attacks, or nonfatal

stroke), and 13% reduction in MACE-4 (a composite of cardiovascular death, nonfatal heart attacks, nonfatal stroke, or coronary revascularization). (FAC ¶ 54; Answer ¶ 54.) On March 4, 2023, Esperion presented the Study’s full results at the American College of Cardiology annual conference and published the results in the *New England Journal of Medicine*. (FAC ¶ 65; Answer ¶ 65.) DSE admits that the Study included multiple “results” that demonstrated “a reduced risk of certain cardiovascular events.” (Answer ¶¶ 28, 54.)

At the October 18, 2023 conference, counsel for DSE conceded to the Court that there is no dispute over the results of the Study: “the results are what they are but the dispute relate[s] to whether those study results were good enough to warrant a large milestone payment under the agreement.” (Oct. 18, 2023 Tr. at 30:25–31:3).

III. DSE Reneges On Its Payment Obligation.

On December 7, 2022, Esperion issued a press release announcing the results of the Study. (FAC ¶ 55; Answer ¶ 55.) On March 8, 2023, DSE told Esperion it would not make the contractually required milestone payment to Esperion. (FAC ¶ 70; Answer ¶ 70.) DSE asserted that the Payment could be triggered by only the Study’s MACE-4 result, not any of the other Study results measuring cardiovascular risk. (FAC ¶ 72; Answer ¶ 72.) According to DSE, because the Study demonstrated a risk reduction rate for MACE-4 below 15%, DSE would not make any Payment to Esperion. (*Id.*)

LEGAL STANDARDS

Rule 12(c) of the Federal Rules of Civil Procedure provides that “a party may move for judgment on the pleadings” any time “[a]fter the pleadings are closed—but early enough not to delay trial.” Fed. R. Civ. P. 12(c). “In deciding a motion under Rule 12(c), the district court may consider only the contents of the pleadings themselves, documents attached to the pleadings as exhibits or incorporated by reference, and items of which judicial notice may be taken.” *Daniels*

ex rel. Daniels v. Comm’r of Soc. Sec., 456 F. App’x 40, 41 (2d Cir. 2012) (citing *Samuels v. Air Transp. Local 504*, 992 F.2d 12, 15 (2d Cir. 1995)).

“Judgment on the pleadings ‘is appropriate where material facts are undisputed and where a judgment on the merits is possible merely by considering the contents of the pleadings.’” *Allstate Ins. Co. v. Vitality Physicians Grp. Prac. P.C.*, 537 F. Supp. 3d 533, 545 (S.D.N.Y. 2021) (citation omitted). Judgment on the pleadings is “particularly appropriate” in contract disputes like this one where a “contract is unambiguous” and “the Court may determine the parties’ rights and obligations as a matter of law.” *See Neopharm Ltd. v. Wyeth–Ayerst Int’l LLC*, 170 F. Supp. 3d 612, 615 (S.D.N.Y. 2016); *VoiceAge Corp. v. RealNetworks, Inc.*, 926 F. Supp. 2d 524, 529 (S.D.N.Y. 2013) (same). A plaintiff’s motion for judgment on the pleadings “should be granted” if the “defendant’s answer admits, alleges, or fails to deny facts which, taken as true, would entitle a plaintiff to relief on one or more claims supported by the complaint.” *Allstate Ins. Co.*, 537 F. Supp. 3d at 545 (citation omitted).

“[T]he threshold question is whether the contract is ambiguous,” which “is a question of law.” *Lockheed Martin Corp. v. Retail Holdings, N.V.*, 639 F.3d 63, 69 (2d Cir. 2011). Where, as here, a contract is unambiguous, “‘courts are required to give effect to the contract as written and may not consider extrinsic evidence to alter or interpret its meaning.’” *U.S. Tr. Co. of New York v. Jenner*, 168 F.3d 630, 632 (2d Cir. 1999) (quoting *Consarc Corp. v. Marine Midland Bank, N.A.*, 996 F.2d 568, 573 (2d Cir. 1993)).

A contract is not rendered ambiguous simply because “the parties interpret a contract provision differently,” *Ambac Assurance Corp. v. U.S. Bank Nat’l Ass’n*, 2023 WL 6162306, at *8 (S.D.N.Y. Sept. 21, 2023), or because one party makes a “[m]ere assertion . . . that contract language means something to him,” *Response Pers., Inc. v. Hartford Fire Ins. Co.*, 812 F. Supp.

2d 309, 314 (S.D.N.Y. 2011). If “the interpretation urged by one party would ‘strain the contract language beyond its reasonable and ordinary meaning,’” that interpretation is not reasonable and the contract should not be interpreted to be ambiguous. *Ambac*, 2023 WL 6162306, at *8 (alteration marks omitted).

ARGUMENT

I. The Agreement Is Unambiguous: “A Result” Could Trigger DSE’s Payment Obligation, Not Only One Particular Result.

The Agreement unambiguously states that any one of many cardiovascular risk reduction results could trigger DSE’s payment obligation, not only one particular result. That is the only reasonable way to read the Agreement in light of its plain language and fundamental canons of contract interpretation. DSE’s contrary interpretation is unreasonable because it asks the Court to rewrite the agreement and to insert language the parties did *not* use, while ignoring the language the parties *did* use. DSE argues that a particular result of the Study—MACE-4—is the sole trigger for its obligation to make the Payment. But the Agreement never mentions the term “MACE-4,” much less anoints it as the sole trigger for a \$300 million payment. DSE cannot “rewrite the terms of the contract with the benefit of hindsight.” *In re Residential Cap., LLC*, 531 B.R. 25, 31 (Bankr. S.D.N.Y. 2015), and its reading should be rejected as unreasonable.

A. The Agreement’s Plain Language And Canons Of Construction Confirm That It Has One Reasonable Reading.

The Court need look no further than the Agreement’s plain language to decide this case. Section 9.2 provides that “a result” of the Study can trigger DSE’s payment obligation. The Agreement does not specify any particular result or otherwise limit the universe of triggering “results.” Well-settled canons of contract construction confirm this plain-language reading.

Plain Language. The Agreement’s plain language resolves this dispute. “[W]hen parties set down their agreement in a clear, complete document, their writing should be enforced according

to its terms.” *Vt. Teddy Bear Co. v. 538 Madison Realty Co.*, 1 N.Y.3d 470, 475 (2004) (citation and ellipsis omitted). “[W]ords and phrases should be given their plain meaning, and the contract should be construed so as to give full meaning and effect to all of its provisions.” *LaSalle Bank Nat. Ass’n v. Nomura Asset Cap. Corp.*, 424 F.3d 195, 206 (2d Cir. 2005) (quotation marks and alterations omitted); *accord Anthem, Inc. v. Express Scripts, Inc.*, 2022 WL 1558879, at *5 (S.D.N.Y. Mar. 31, 2022) (Ramos, J.) (same). “A written agreement that is clear, complete, and subject to only one reasonable interpretation must be enforced according to the plain meaning of the language chosen by the contracting parties.” *Brad H. v. City of New York*, 17 N.Y.3d 180, 185 (2011). Courts “apply this rule with even greater force in commercial contracts” like this one, “negotiated at arm’s length by sophisticated, counseled businesspeople.” *Ashwood Cap. Inc. v. OTG Mgmt., Inc.*, 99 A.D.3d 1, 7 (1st Dep’t 2012). (See FAC ¶ 35; Answer ¶ 35.)

The Agreement’s plain language is subject to only one reasonable interpretation. Section 9.2 provides that DSE will owe the Payment if “*a* result of the CLEAR Outcome Study” meets the contractual thresholds. (Agmt. § 9.2 (emphasis added).) The ordinary meaning of the indefinite article “a” modifying the noun “result” unambiguously reflects the parties’ understanding that the Study would yield multiple results reflecting cardiovascular risk reduction and that any one of those results could trigger the Payment. The Oxford English Dictionary defines the indefinite article “a” as “referring to something not specifically identified . . . but treated as one of a class: one, some, any.” *A*, Oxford English Dictionary (3d ed., June 2008), https://www.oed.com/dictionary/a_adj; see also *Anthem, Inc.*, 2022 WL 1558879, at *5 (“New York courts will commonly refer to dictionary definitions” to determine the “plain and ordinary meaning” of contractual terms). Here, the parties used the word “a” in its natural and everyday sense to confirm that “a result” meant any one result of several.

For well over a century, New York courts have construed the word “a” in exactly this way, explaining that “use of the indefinite article . . . ‘a’” refers “to any one of” several possibilities. *Van Brunt v. Van Brunt*, 111 N.Y. 178, 185 (1888) (“[T]he indefinite article in the phrase ‘a husband or wife’ was occasioned by the existence of several such persons answering the description, to any one of whom the provision was intended to apply.”); *see also CSX Transp., Inc. v. Island Rail Terminal, Inc.*, 879 F.3d 462, 471 (2d Cir. 2018) (“The use of the definite article ‘the’ indicates a singular [entity], whereas the indefinite article ‘any’ or ‘a’ denotes multiple [entities]”); *Ish Yerushalayim v. United States*, 374 F.3d 89, 92 (2d Cir. 2004) (“A ‘State’ means ‘any of the several States’” (citation omitted)); *Holsman v. St. John*, 90 N.Y. 461, 463 (1882) (“‘A party’ means any party or parties, one, two, three or all.”).

In this case, by using “the indefinite article ‘a,’” the Agreement confirms “the modified noun”—here, “a result of the . . . Study,” (Agmt. § 9.2)—“is but one of several of that kind.” *Renz v. Grey Advert., Inc.*, 135 F.3d 217, 222 (2d Cir. 1997). The dictionary definition and the caselaw thus make clear if **one** Study result out of many meets the risk-reduction thresholds, and is reflected in the label, DSE will owe the Payment.

Other provisions in the Agreement confirm that when these sophisticated parties meant to specify particular results in the Agreement, they knew how to do so and did so. Their decision not to use similar limiting language in Section 9.2 is “strong evidence that the omission was intentional,” and should be respected. *Avon Co. v. Fareva Morton Grove, Inc.*, 2022 WL 2208156, at *6 (S.D.N.Y. June 21, 2022) (“These are sophisticated parties that plainly knew how to be specific and impose limitations in other provisions,” so “[t]heir failure to impose such a limitation or obligation in [Section 9.2] is strong evidence that the omission was intentional.”). For example, Section 7.2.1 specifically states that the parties “may publish *certain key results* achieved in

connection with this Agreement” and that “either Party wishing to make a publication or public presentation regarding *any such key results* . . . shall deliver to the other Party” a copy of the material 45 days beforehand. (Agmt. § 7.2.1 (emphasis added).) Likewise, in describing the press releases each party would issue upon executing the Agreement, the parties specified how they would characterize particular results of prior clinical studies, agreeing that they would publicly state that the studies had demonstrated “a 35 percent lowering of LDL-C when used with maximally tolerated statins, a 43 percent lowering of LDL-C when used as a monotherapy, and a 34 percent reduction in high sensitivity C-reactive protein (hsCRP).” (Agmt. Sched. 7.3.) Finally, in discussing planned clinical studies, Schedule 2.1.1 includes two “Study Titles” that reference an “endpoint” of “absolute change in HbA1c as compared to placebo.” (Agmt. Sched. 2.1.1.)

Section 9.2 does not include *any* of this limiting language: “certain key results,” “such key results,” specific study results, or “endpoint.” This limiting language—which occurs through the Agreement, but not in Section 9.2—demonstrates that when the parties wanted to specify a particular result, they knew how to do so and did so, and their decision not to do so in Section 9.2 was knowing and intentional.

If Esperion and DSE had intended to make one specific and particular result the only triggering event under Section 9.2, they easily could have followed their practice and included limiting language to that effect. The English language has many ways to communicate specificity, particularity, and limitation. For example, the parties could have used the specific words “MACE-4” or “primary endpoint.” They could have employed a capitalized defined term. They could have drafted language expressly including certain results, or expressly excluding others. Esperion and DSE knew that the study would have multiple results, *see* Answer ¶¶ 28, 54, yet they did not take any of those steps to particularize or limit the result or results that trigger DSE’s payment

obligation. Instead, they used the indefinite article “a” with none of the limiting language used in other provisions of the Agreement. That was a deliberate choice, not an error or oversight.

The parties’ intentional use of the indefinite article “a” is dispositive. Over a century of case law, the dictionary, and common sense make clear that the indefinite article “a” refers one of several results, and not one particular result that does not even appear in the document. *See infra* 9–10.

Canons of Construction. Fundamental canons of construction—the general-terms canon and the canon against surplusage—confirm that the Agreement is unambiguous and Esperion’s plain-language interpretation is correct. *See RM Realty Holdings Corp. v. Moore*, 64 A.D.3d 434, 437 (1st Dep’t 2009) (looking to “well-settled canons of contract interpretation” in concluding that agreement was unambiguous); *Lend Lease (US) Constr. LMB Inc. v. Zurich Am. Ins. Co.*, 136 A.D.3d 52, 57 (1st Dep’t 2015) (applying canon to hold contract unambiguous).

The general-terms canon requires that general terms in a contract “are to be accorded their full and fair scope” and “are not to be arbitrarily limited.” Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 101 (2012); *see also United States v. Weiss*, 52 F.4th 546, 552 (3d Cir. 2022) (“[G]eneral terms should be interpreted generally.”); *Arizona v. Tohono O’odham Nation*, 818 F.3d 549, 557 & n.4 (9th Cir. 2016) (“General words are to be understood in a general sense.”); *In re Lehman Bros. Inc.*, 478 B.R. 570, 588 (S.D.N.Y. 2012) (“[I]f the parties had meant” to use a term “in a specific sense,” “they could have—and should have—said so.”). Here, the parties used the general term “a result,” rather than a specific, technical term such as MACE-4. The general-terms canon requires that the term “a result” be given its full scope and not arbitrarily limited to mean one particular result out of a group of results.

The canon against superfluity counsels against contract interpretations that would render any provision “superfluous or meaningless.” *LaSalle Bank*, 424 F.3d at 206 (quoting *Shaw Grp., Inc. v. Triplefine Int’l Corp.*, 322 F.3d 115, 124 (2d Cir. 2003)). Here, Esperion’s reading gives effect to all of Section 9.2, including the provision that “[t]he milestone payment shall be payable only once.” (Agmt. § 9.2.) The “payable only once” provision specifies that no matter how many different Study results demonstrate cardiovascular risk reduction above the contractual thresholds, DSE has to make only one payment. DSE’s reading would render that provision superfluous and meaningless. If only one particular result of the study could trigger DSE’s payment obligation, as DSE says, there would have been no need to provide that the “milestone payment shall be payable only once.”²

B. DSE’s Contrary Reading Is Not Reasonable.

DSE argues that its obligation to make the Payment depends on *one and only one result* from the Study—the MACE-4 composite result for cardiovascular death, nonfatal heart attacks, nonfatal stroke, and coronary revascularization. The Court should reject DSE’s reading as unreasonable. *See Ambac*, 2023 WL 6162306, at *8 (if “the interpretation urged by one party would ‘strain the contract language beyond its reasonable and ordinary meaning,’” that interpretation is not reasonable and the contract should not be interpreted to be ambiguous (alteration marks and citation omitted)).

² In fact, the Study did produce multiple results demonstrating “cardiovascular risk reduction,” (Agmt. § 9.2), including “a 27% reduction in non-fatal heart attacks and 23% reduction in the composite of nonfatal and fatal heart attacks.” (FAC ¶ 54; Answer ¶ 54 (“admit[ting] that . . . the Study results showed that patients . . . had a reduced risk of certain adverse cardiovascular events”).) This limiting language will work precisely as the parties contemplated: although multiple results of the Study exceed the contractual thresholds, DSE will owe only one \$300 million payment to Esperion, not a series of \$200 and \$300 million payments.

Section 9.2 does not say that DSE will owe the payment based on “the MACE-4 result” of the Study. Section 9.2 does not even mention the term MACE-4. Nor does any other provision of the Agreement—the entire 84-page Agreement never mentions MACE-4 once. Reading the terms of Section 9.2 as DSE urges—to mean only MACE-4—would “require the addition of concepts not set forth in the agreement[] and the importation of language from outside sources.” *In re Lehman Bros. Inc.*, 478 B.R. at 588. Because “a plain four-corners reading does not support” DSE’s interpretation of the Agreement, *see Anthem*, 2022 WL 1558879, at *7, it should be rejected.

DSE’s reading also violates bedrock principles of contract construction. “[C]ourts should be extremely reluctant to interpret an agreement as impliedly stating something which the parties have neglected to specifically include.” *Rowe v. Great Atl. & Pac. Tea Co.*, 46 N.Y.2d 62, 72 (1978). The parties—two sophisticated pharmaceutical companies that were certainly well aware of the concept of MACE-4—could easily have specified that the sole event triggering the payment obligation was the MACE-4 result, but they chose not to do so. DSE’s after-the-fact attempt to revise the Agreement’s language under the guise of contract “interpretation” is impermissible and would amount to adding a term that is “simply nowhere to be found in the relevant provisions of the contract.” *Impax Lab’ys, Inc. v. Turing Pharms. AG*, 2017 WL 4357893, at *10 (S.D.N.Y. Sept. 29, 2017) (Ramos, J.).

In its pre-motion letter, DSE discussed a purported distinction between “primary” and “secondary” endpoints in the context of clinical studies, and how a “rational pharmaceutical company” would have interpreted the difference between them. Dkt. 73 at 1–2. But Section 9.2 does not refer to any “primary” or “secondary” endpoint—just as it does not refer to MACE-4—or distinguish between those measures. Here too, DSE’s reading would “require the addition of concepts not set forth in the [A]greement[.]” *In re Lehman, Bros.*, 478 B.R. at 588. DSE also

argued in its pre-motion letter that the phrase “the relative risk reduction rate” in the Agreement means the parties intended “one relative risk reduction rate [to] matter[] for the purposes of the milestone payment[.]” Dkt. 73 at 3. But DSE’s truncated quotation—an interpretative sleight of hand—cuts out the next two words in the phrase: “the relative risk reduction rate *indicated below*.” Read in full, this phrase simply refers to the two specific contractual thresholds “indicated below,” in the table at the bottom of Section 9.2:

9.2. Regulatory Milestone Payment. Esperion will provide DSE with written notice of the achievement of the following regulatory milestone event within ten (10) days after such event has occurred. Esperion shall invoice DSE within thirty (30) days of receipt of such written notice, and DSE shall pay the associated milestone payment within thirty (30) days following receipt of such invoice. This milestone payment shall be payable only once.

Regulatory Milestone Event	Milestone Payment
Grant of the first Regulatory Approval in the DSE Territory of a Licensed Product that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as a result of the CLEAR Outcome Study:	
Equal to or greater than 15% and less than 20%	\$200,000,000
Equal to or greater than 20%	\$300,000,000

The phrase “the relative risk reduction rate indicated below” simply references the specific contractual thresholds of 15% and 20%. And the other terms of Section 9.2 unambiguously explain that “a result” of the Study that meets those thresholds requires DSE to pay Esperion—without specifying which result or excluding some results from contention.

DSE “strain[s] the contract language beyond its reasonable and ordinary meaning.” *Ambac*, 2023 WL 6162306, at *8 (citation omitted), in an effort to create ambiguity where none exists. This Court should reject DSE’s interpretation and enforce the Agreement’s plain and unambiguous language.

II. Judgment On The Pleadings Is Warranted And Urgently Needed.

The parties’ dispute is ripe for resolution now. Both the threshold determination of whether the Agreement is unambiguous, as well as the interpretation of the Agreement’s unambiguous

terms, are pure questions of law that the Court can and should decide now. *See Surrey Propco LLC v. Denihan Ownership Co., LLC*, 614 F. Supp. 3d 62, 69 (S.D.N.Y. 2022) (“When a contract governed by New York law is unambiguous, the meaning of that contract ‘is a question of law that the Court may decide’ on a . . . Rule 12(c) motion.” (internal citation omitted)); *Cue Fashions, Inc. v. LJS Distrib., Inc.*, 807 F. Supp. 334, 336 (S.D.N.Y. 1992) (“grant[ing]” motion “pursuant to Rule 12(c)” because “the pertinent clause of the policy at issue is unambiguous and its plain language precludes” opposing party’s position).

There are no fact disputes that would prevent the Court from entering judgment on the pleadings. It is undisputed that multiple results of the Study demonstrated cardiovascular risk reduction in excess of the contractual thresholds. DSE admitted in its Answer that the CLEAR Outcomes Study included multiple “results” that demonstrated “a reduced risk of certain adverse cardiovascular events.” (Answer ¶ 54.) And DSE’s counsel further admitted at the October 18, 2023 pre-motion conference that “the results are what they are.” (Oct. 18, 2023 Tr. at 30:25.)

DSE’s only response is that none of those results matters, because only the MACE-4 result—which, it just so happens, fell below the contractual threshold—could possibly trigger DSE’s payment obligation. But saying it over and over does not make it so. That defense is based purely on a (strained and unreasonable) interpretation of the contract language. The Court can resolve this dispute by determining what the Agreement means as matter of law. And the Court should hold that DSE’s reading is unreasonable and the Agreement unambiguously requires DSE to make the payment if “a result” of the Study—not only one particular result—shows cardiovascular risk reduction above the contractual thresholds.

In its pre-motion letter, DSE says that “material facts are disputed,” Dkt. 73 at 1—but fails to identify a single disputed fact that is material to the interpretation of Section 9.2. DSE also

makes much of the fact that Esperion’s complaint refers to certain drafts of the Agreement and other documents. *See id.* at 2. But the fact that Esperion’s pleading references certain extrinsic evidence is not relevant to determining whether the terms of Section 9.2 themselves are unambiguous, which is a pure question of law that must be determined based on the four corners of the contract. *See Kass v. Kass*, 91 N.Y.2d 554, 566 (1998) (“Ambiguity is determined by looking within the four corners of the document, not to outside sources.”).

Extrinsic evidence can only be considered to determine the parties’ intent where a contract is ambiguous. By contrast, where “an agreement is unambiguous, courts should not consider extrinsic evidence to determine the parties’ intent.” *Fineman Family LLC v. Third Ave. North LLC*, 90 A.D.3d 549, 551 (1st Dep’t 2011) (holding that where contract is unambiguous, the trial court “improperly considered the averments of plaintiff’s president”). Here, for the reasons set forth above in Part I, Section 9.2 is not ambiguous. As a result, the Court does not need to and should not consider any extrinsic evidence to interpret the unambiguous language of Section 9.2 of the Agreement. The plain, ordinary meaning of Section 9.2 controls the outcome here, and the canons of contractual interpretation lead to the same conclusion. No extrinsic evidence is necessary or appropriate. *See Luitpold Pharms., Inc. v. Ed Geistlich Sohne A.G. Fur Chemische Industrie*, 784 F.3d 78, 87–88 (2d Cir. 2015) (“Only when a court finds ambiguity in the parties’ written agreement may it look to extrinsic evidence to discern the parties’ intent.”).

Declaratory judgment in Esperion’s favor would resolve this dispute, plainly serving “a useful purpose in clarifying or settling the legal issues involved” and bringing this “controversy” and the attendant “uncertainty” to an end. *Duane Reade, Inc. v. St. Paul Fire & Marine Ins. Co.*, 411 F.3d 384, 389 (2d Cir. 2005). But declaratory judgment is not just appropriate—it is urgently needed. The day the markets learned DSE had announced it would not make the Payment to

Esperion, Esperion's stock price fell by 54%.³ It has fallen by more than another 50% since then, and is now trading below \$1. Every day this dispute remains unresolved diminishes the odds of Esperion's continued existence and in turn imperils its life-saving drugs from reaching patients who desperately need them.

As this litigation has unfolded, the costs associated with it have come to represent a more significant threat to Esperion's survival than Esperion could have anticipated. *See Bey v. City of New York*, 2010 WL 3910231, at *3 (S.D.N.Y. Sept. 21, 2010) (“[R]eaching the merits of Defendants’ 12(c) motion serves the interest of judicial economy and may save the parties unnecessary time and expense which otherwise would be incurred during trial.”). DSE has repeatedly forced Esperion to shoulder significant, disproportional discovery burdens—for example, DSE has demanded that Esperion review nearly four times as many documents as DSE agreed to review. DSE has engineered an unusual, and unfair, mismatch in discovery burden between these two corporate parties—a burden that Esperion is far less able to bear financially than DSE is. That burden will continue to expand in the months of discovery ahead. The parties are currently scheduled to take at least 20 fact depositions over six weeks across multiple cities—in California, Michigan, New York, and Brussels. And the subsequent expert discovery stage will prove just as demanding. It is now clear litigating this case through to summary judgment and trial in 2024 will cost millions of dollars that Esperion can scarcely afford. And if past is prologue, the litigation will likely continue to generate disputes that require the Court’s intervention to resolve.

It is not necessary to commit such significant resources from the parties and the Court to

³ *Esperion (ESPR) Plummets 54% Over Milestone Payment Row*, NASDAQ (Mar. 17, 2023), <https://tinyurl.com/mvkbfw4d>.

this dispute when DSE's obligations to Esperion turn on a pure question of law that can and should be resolved on the face of the contract and pleadings. *See, e.g., FaceTime Comm'cns, Inc. v. Reuters Ltd.*, 2008 WL 2853389, at *4 (S.D.N.Y. July 22, 2008) (granting declaratory judgment to plaintiff because the contract at issue was "clear and can be easily adjudicated as a simple matter of contract construction," "the issues here are ripe for adjudication," and "there is no reason for delay").

CONCLUSION

The Court should enter declaratory judgment in Esperion's favor, declaring that any result of the CLEAR Outcomes Study demonstrating cardiovascular risk reduction that meets the contractual thresholds satisfies the requirements of Section 9.2 of the Agreement to trigger DSE's obligation to make the Payment to Esperion.

Dated: New York, New York
October 25, 2023

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